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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,316	11/13/2003	Hugh S. West JR.	ZL0253	1989
23367	7590	01/12/2006	EXAMINER	
GENE WARZECHA LINVATEC CORPORATION 11311 CONCEPT BOULEVARD LARGO, FL 33773			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,316	<b>Applicant(s)</b> WEST ET AL.	
	<b>Examiner</b> Alex B. Toy	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 7, 14, 23, 24 and 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-13, 15-22 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The inventor Hugh S. West, Jr. has failed to sign and date the oath.

### ***Election/Restrictions***

Applicant's election of Species I shown in Figs. 1-22 in the reply filed on October 14, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 7, 14, 23-24, and 30-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

In summary, claims 7, 14, 23-24, and 30-33 are withdrawn from further consideration. Claims 1-6, 8-13, 15-22, and 25-29 are examined.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. It is unclear what comprises an axial plane given the geometric definitions of plane and axis. In other words, it is not possible for a plane to be an axis. For the purposes of examination, it is assumed applicant intended claim 5 to read: "wherein said axis lies in said plane." If this is the case, then claim 5 would be withdrawn from consideration as being drawn to nonelected Species II or III shown in Figs. 23A and 24A-24B, respectively. In this first Office Action, however, the examiner has decided to examine claim 5 on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-13, 15-22, and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (U.S. Pat. No. 6,110,170).

Regarding claim 1, Taylor discloses an electrode comprising:

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an elongated shaft 16 having an axis, a proximal end and a distal end;

electrical conducting means 200, 202 for conducting electrical energy from said proximal end to said distal end (col. 11, ln. 15-19); and

at least one electrode member 202 secured relative to said distal end of said shaft and to said electrical conducting means, said at least one electrode curved convexly 18 relative to said shaft axis.

See Figs. 15A and 17A.

The claim differs from Taylor in calling for the electrode to be a radiofrequency electrode. Taylor does not expressly disclose that the electrode is a radiofrequency electrode but specifies that "a suitable energy source" is used (col. 11, ln. 17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the electrode of Taylor a radiofrequency electrode because radiofrequency energy is an obvious suitable energy source that is well-known in the art.

Regarding claim 2, Taylor discloses the electrode according to claim 1 as shown above. Taylor further discloses the electrode, wherein said electrode member 212 has an outward surface facing away from said axis and an inward surface facing toward said axis, further comprising an insulating member 18 interposed between said inward surface and said distal end of said shaft (col. 11, ln. 39-48 and Figs. 17A-17B).

Regarding claim 3, Taylor discloses the electrode according to claims 1 and 2, wherein said insulating member 18 comprises a channel 214 for supporting said electrode member (Figs. 17A-17B).

Regarding claim 4, Taylor discloses the electrode according to claim 1, wherein said electrode member is elongated and lies in a plane (Figs. 17A-17B).

Regarding claim 5, Taylor discloses the electrode according to claims 1 and 4, wherein said axis lies in said plane (Figs. 17A-17B).

Regarding claim 6, Taylor discloses the electrode according to claims 1 and 4, wherein said plane is parallel to said axis (Fig. 26C).

Regarding claim 8, Taylor discloses the electrode according to claim 1, wherein said electrode member is a wire-like member (col. 11, ln. 43-50).

Regarding claim 9, Taylor discloses the electrode according to claim 1, wherein said electrode member is curved in one dimension only (Figs. 17A-17B).

Regarding claim 10, Taylor discloses the electrode according to claim 1, wherein a first portion of said electrode member faces proximally and a second portion of said electrode member faces distally (Fig. 17A).

Regarding claim 11, Taylor discloses the electrode according to claims 1 and 10, wherein the surface 208 of said distal end of said shaft is spaced a first predetermined distance from said axis and wherein at least a part of said first portion of said electrode member 212 is spaced a second predetermined distance from said axis, said second predetermined distance being greater than said first predetermined distance (Fig. 17A).

Regarding claim 12, Taylor discloses the electrode according to claim 1 further comprising:

a longitudinally extending lumen 234 (Fig. 19A);

an aspiration port 236 situated adjacent said electrode member and in communication with said lumen (Fig. 20); and

aspirating means to aspirate ablation by-products through said lumen (col. 12, ln. 37-40).

Regarding claim 13, Taylor discloses the electrode according to claims 1 and 12, wherein said lumen is within said shaft (Figs. 19A and 20).

Regarding claim 15, Taylor discloses an ablation device comprising:

a handle 14;

an elongated shaft 16 extending from said handle, said shaft having a proximal end attached to said handle and a distal end, said distal end terminating in a generally cylindrical closed end;

an electrode supporting member 18 secured to said distal end, said electrode supporting member having an inner surface for conforming to said distal end and an outer bulbous surface for supporting at least one electrode 212; and

at least one electrode member 212 secured relative to and conforming to said bulbous electrode supporting surface, said electrode member having a proximal end and a distal end and adapted to receive electrical energy from a source thereof.

See Figs. 15A and 17A-17B. See the preceding rejection of claim 1 regarding the type of energy claimed. In addition, since the device of Taylor uses an electrode to cut through vessels (col. 4, ln. 52-62), it inherently ablates tissue in the cutting process. If not inherent to the cutting process, the device is inherently capable of ablation, and it would be an obvious way of using the device that requires only routine skill in the art.

Regarding claim 16, Taylor discloses the device according to claim 15, wherein said electrode member is a coil-like member and further comprising two said coil-like members (Fig. 26C). The claim differs from the Taylor electrodes shown in Fig. 26C in calling for the electrodes to be wire-like. Taylor, however, also teaches an analogous electrode comprising wire (col. 11, ln. 43-50 and Fig 17A). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the Taylor electrodes shown in Fig. 26C from wire instead of coils as an obvious alternate configuration that is suitable and suggested as interchangeable by Taylor.

Regarding claim 17, Taylor discloses the device according to claims 15 and 16, wherein said electrode members are parallel (Fig. 26C).

Regarding claim 18, Taylor discloses the device according to claims 15-17, wherein said electrode members are axially aligned (Fig. 26C).

Regarding claim 19, Taylor discloses the device according to claim 15, wherein said bulbous electrode supporting surface 18 is a high temperature insulating material (col. 11, ln. 39-40 and Fig. 17A). Taylor specifically teaches that the analogous bulbous electrode supporting surface 340 shown in Fig. 27B is electrically non-conductive (col. 16, ln. 19-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the bulbous electrode supporting surface 18 of Fig. 17A from an electrically non-conductive material as an obvious material that is suitable and suggested by Taylor in Fig. 27B.



Regarding claim 20, Taylor discloses the device according to claims 15-17, wherein said electrode members each have a conducting surface parallel to and spaced a predetermined amount away from said insulating surface (Figs. 17A and 26C).

Regarding claim 21, Taylor discloses an ablation device according to claim 15 wherein said ablation device operates in a liquid medium and further comprising:

an aspiration means for aspirating ablation by-products from said liquid medium, said aspiration means comprising:

at least one distal port 236 situated at said distal end of said shaft (Fig. 20);

a longitudinally extending lumen 234 on said shaft, said lumen operatively connected to said distal port (Fig. 19A); and

means for aspirating ablation by-products through said distal port and said lumen (col. 12, ln. 37-40).

The device of Taylor is inherently capable of operating in a liquid medium and aspirating ablation by-products from said liquid medium.

Regarding claim 22, Taylor discloses an ablation device according to claim 15, wherein said electrode member is a monopolar electrode (col. 11, ln. 56-57).

Regarding claim 25, Taylor discloses an ablation device according to claim 15, wherein said distal end of said elongated shaft has an outer cylindrical surface spaced a first predetermined radial distance from said axis, and wherein said bulbous electrode supporting surface has a portion thereof at a second predetermined radial distance from said axis, said second predetermined distance being greater than said first predetermined distance (Fig. 17A).

Regarding claim 26, Taylor discloses the device according to claims 15 and 25, wherein said distal end has a first predetermined width in a first plane and a second predetermined width in a second plane perpendicular to said first plane, said first predetermined width being greater than said second predetermined width (Fig. 19A). In addition, applicant has not disclosed any criticality or unexpected result associated with these limitations.

Regarding claim 27, Taylor discloses the device according to claims 15, 25, and 26, further comprising at least one aspirating port 236 in the portion of said distal end having said first predetermined width (Fig. 20).

Regarding claim 28, Taylor discloses the device according to claims 15 and 25-27. Taylor does not expressly disclose an aspirating port on opposed sides of said portion of said distal end. At the time the invention was made, however, it would have been an obvious matter of design choice to a person of ordinary skill in the art to place an aspirating port on opposed sides of said portion of said distal end of Taylor because applicant has not disclosed that this particular arrangement has any criticality or unexpected result. Applicant further discloses that alternatively, distal end 26 could be open thereby obviating the need for aspiration ports 30 (pg. 13, ln. 5-7). This arrangement would be analogous to the Taylor device shown in Fig. 20. Consequently, one of ordinary skill in the art would have expected applicant's invention to perform equally well with the ports as claimed or as shown by Taylor in Fig. 20. Therefore, it would have been an obvious matter of design choice to modify Taylor to obtain the invention as specified in claim 28.

Regarding claim 29, Taylor discloses a monopolar electrode for use with an electrosurgical pencil connected to an electrosurgical generator comprising:

a shaft 16 having an axis, a distal end and a proximal end, said proximal end adapted to be connected to said electrosurgical pencil 14, said distal end terminating in a partially bulbous end having a bulbous electrode supporting surface 18 (Fig. 15A);  
and

a pair of wire-like electrode members 314, 316 substantially conforming to said bulbous electrode supporting surface, said electrode members adapted to receive radiofrequency electromagnetic energy from a source thereof (Fig. 26C). Regarding the electrodes being wire-like, see the rejection of claim 16. Regarding the type of energy, see the rejection of claim 1.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 5281216 A	USPAT	Kliceck; Michael S.
US 5499981 A	USPAT	Kordis; Thomas F.
US 5542945 A	USPAT	Fritzsche; Gernod
US 5906615 A	USPAT	Thompson; Todd
US 5944715 A	USPAT	Goble; Nigel Mark et al.
US 6210405 B1	USPAT	Goble; Nigel M. et al.

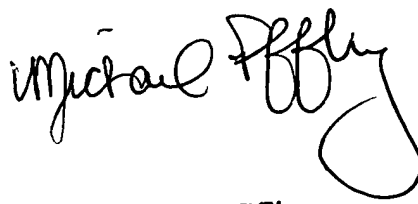
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Michael Peffley". The signature is stylized with a large loop at the end.

MICHAEL PEFFLEY  
PRIMARY EXAMINER